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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,981	08/21/2003	Bernd Sundermann	029310.52539US	6366

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EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/644,981	Applicant(s) SUNDERMANN ET AL.	
	Examiner Charanjit S. Aulakh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-23,30,31,35 and 36 is/are rejected.
- 7) ☒ Claim(s) 1-13,24-29 and 32-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. According to paper filed on May 2, 2005, the applicants have elected group IV with traverse for further prosecution in response to restriction requirement.

Response to Arguments

2. Applicant's arguments filed on May 2, 2005 have been fully considered but they are not persuasive regarding restriction requirement. The examiner does not agree with the applicants arguments that all groups share the common core. The specific values of variables R1, R2, R3, R4, R5 and R6 are critical for the common core of the instant compounds as stated in the last office action since the structures are so divergent based on the specific values of these variables and furthermore, are classified in different classes and subclasses and therefore, does constitute a burdensome search. Thus, restriction requirement as indicated is proper and thereby made final.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 35 and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating pain, does not reasonably provide enablement for inhibiting pain or treating urinary incontinence, itching, tinnitus, aurium and diarrhea. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see Ex parte Foreman,

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230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, the state of the prior art and the breadth of claims.

The specification teaches analgesic activity of instant compounds in the writhing test in the mouse (see pages 53 and 54) and therefore, the instant compounds will have utility in treating but not inhibiting pain. There is no teaching regarding any specific mechanism of action (such as agonist or antagonist activity at specific receptors, enzyme inhibition etc.) of instant compounds either in the specification or prior art reference. The specification mentions on page 4 regarding some specific compounds in the prior art encompassed by the instant compounds of formula I. However, no pharmacological utility is mentioned in this reference. It is well known in the art that there are numerous mechanisms involved in the etiology of any known disease condition such as pain and therefore, correcting one mechanism only will not inhibit (completely cure) that specific disease condition. There is no teaching either in the specification or prior art regarding efficacy of instant compounds in known animal models of urinary incontinence, itching, tinnitus, aurium and diarrhea. There are no

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working examples present to show efficacy of instant compounds in known animal models of any other disease condition except for analgesic activity. There is no guidance present how the instant compounds having analgesic activity will have utility in treating urinary incontinence, itching, tinnitus, aurium and diarrhea. The instant compounds of formula I encompasses hundreds of thousands of compounds based on the values of variables m, R3, R4, R5, R6 and A and therefore, in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to demonstrate the efficacy of instant compounds in known animal models of urinary incontinence, itching, tinnitus, aurium and diarrhea and hence their utility for treating these disorders.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 35 and 36, it is not clear what is being treated or administered? Is it a human, animal, fish etc? Also, the applicants are suggested to insert ---therapeutically--- before effective amount.

In claim 35, the term ---inhibiting--- is indefinite since the degree of inhibition (20%, 40%, 60%, 80% or 100%)is not defined and furthermore, it is not clear how this inhibition is being assessed?

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 14-23, 30 and 31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Merla (Synlett, cited on applicants form 1449).

Merla discloses a simple and highly diastereoselective one-pot synthesis of 1,3-diamines. The preparation of compounds of formula 4 by aminoalkylation of enamines 2 with ternary iminium salts 1 and reduction of resulting compounds of formula 3 disclosed in scheme and table (see page 177) clearly anticipates the instant claims.

8. Claims 1-36 are objected for containing non-elected subject matter.

Allowable Subject Matter

9. The following is a statement of reasons for the indication of allowable subject matter:

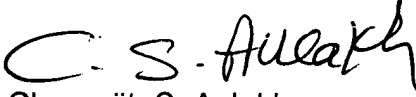
The instant compounds of formula I directed to the elected subject matter are allowable over the prior art since they are neither disclosed nor obvious over the prior art. In the prior art, Merla (Synlett, cited on applicants form 1449) discloses compound 5a (see page 178) which does anticipate the instant compounds. However, this compound has been excluded by a proviso. On the other hand, Merla (Synthesis) discloses compounds in tables 1 and 2 and a process for their preparation (see pages 1366-1367) which do anticipate the instant compounds. However, this publication is inventor's own work and furthermore, does not constitute a prior art reference since it was published (Aug. 1, 2002) much later than the effective filing date (Feb. 21, 2001) of the instant application.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charanjit S. Aulakh
Primary Examiner
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